

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY  
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT  
POLICY

Voluntary    Public

**Date:** 8/1/2013

**GAIN Report Number:** 13036

## **China - Peoples Republic of**

**Post:** Beijing

### **Administrative Measures for Safety Review of New Food Materials**

**Report Categories:**

Policy and Program Announcements

**Approved By:**

Michael Riedel

**Prepared By:**

M. Meador and Ma Jie

**Report Highlights:**

The newly established National Health and Family Planning Commission (NHFPC) issued its first decree on May 31, 2013, announcing the Administrative Measures for Safety Review of New Food Materials. The Measures provide for requirements for safety review of new food materials.

The Measures replaces the Administrative Measures on Novel Food published by the former Ministry of Health on December 1, 2007.

This report provides an unofficial translation of the NHFPC public notice.

**General Information:**

**BEGIN TRANSLATION**

**Administrative Measures for Safety Review of New Food Materials**

National Health and Family Planning Commission Decree No.1

The “Administrative Measures for the Safety Review of New Food Materials” was passed in the ministerial meeting of the former Ministry of Health on February 5, 2013, and is hereby published. These measures will come into force on October 1, 2013.

Li Bin, Minister of NHFPC

May 31, 2013

**Administrative Measures for Safety Review of New Food Materials**

Article 1 These Measures are formulated pursuant to the Food Safety Law and its implementation materials to regulate the review of the safety assessment materials for new food materials.

Article 2 New food materials refer to the following objects/materials that are not traditionally consumed in China:

1. Animal, plant and microorganisms;
2. Substances derived from animals, plants and microorganisms;
3. Food substances whose structure has changed;
4. Other newly developed food materials.

Article 3 New food materials shall have attributes of food materials, and comply with relevant nutrition requirements; the materials shall be toxin-free and harmless, and shall not cause any acute, sub-acute, chronic or other latent health hazards.

Article 4 New food materials shall be used for food production and trade only after passing a safety review by the National Health and Family Planning Commission (NHFPC).

Article 5 NHFPC is in charge of the review and approval of new food materials safety assessment application dossiers.

The Hygiene Supervision Center of NHFPC will accept application materials for new food material safety assessment, and organize a review of the safety assessment dossiers.

Article 6 Any entity or individual person planning to engage in new food material production, use or import shall submit dossiers along with the following materials:

1. Application form;
2. Report regarding research and production of the new food materials;
3. Safety assessment report;
4. Production techniques;
5. Relevant standards (safety, quality, specifications, and testing methods, etc.);
6. Label and instructions;
7. Status on research and production at home and abroad, as well as safety related documents;
8. Other materials that facilitate the review.

Also, a sealed product sample or (packed) 30-gram raw materials shall be submitted.

Article 7 Applicants applying for importation of new food materials shall also submit the following materials in addition to materials provided in Article 6:

1. Certificates issued by the competent authority or organization proving that production and distribution of the product are permitted in the exporting country (region);
2. Audit or licensing certificate issued to the producing enterprises by the competent authority or organization of the country/region where the producer is located;

Article 8 Applicants shall guarantee truthfulness of the submitted materials, which provides a faithful description of the food product; the applicant shall take legal responsibility for the dossier.

Article 9 Applicants shall, in submitting materials provided in Article 6.1.2 to 6.1.6, indicate whether the material is business proprietary, and whether the material can be accessed by the public.

Article 10 NHFPC, after accepting application for a new food material, shall solicit public comments.

Article 11 NHFPC shall, within sixty (60) days after accepting the application, organize experts to review the safety of the new food material; a review conclusion shall be made after the review.

Article 12 Should supplemental materials be needed for the review, the applicant shall be informed in writing in a timely manner; the applicant shall timely submit relevant materials as required.

If necessary for the review, the applicant may be invited to the review site to cooperate in answering relevant technical questions.

Article 13 In the review, if necessary, (the Hygiene Supervision Center) shall organize experts to conduct an on-site verification to study research and production of the new food material and draft an on-site verification opinion. The experts and provincial NHFPC shall cooperate and are responsible for the on-site verification opinions.

Experts conducting the on-site verification shall not attend the meeting that takes place for the vote of the safety assessment dossier of the material.

Article 14 Specific procedures for review and approval of new food material safety assessment materials shall be in compliance with pertinent provisions, such as the “Administrative Measures on Hygiene Administration Permits” and the “Procedures on Hygiene Administration Permit.”

Article 15 NHFPC, based on conclusions of the new food material safety assessment, shall grant approval to materials that comply with food safety requirements, and issue a public notice thereof; NHFPC will provide a written response with reasons to materials that fail to comply with food safety requirements.

NHFPC can terminate a review of materials that are *de facto* equivalent to other foods or to new food materials that have already been approved in a public notice.

Article 16 Pursuant to characteristics of the new food materials, the public notice shall contain the following information:

1. Material name;
2. Source;
3. Production technique;

4. Ingredients;
5. Requirements on quality specifications;
6. Requirements on label;
7. Other information that shall be publicly notified.

Article 17 NHFPC shall conduct a timely reassessment of new food materials that have already been publicly notified if one of the following circumstances occurs:

1. Science and technology advancement generate questions about the safety of the new food material;
2. Evidence proves that the new food material may have a safety problem;
3. Other circumstances that require reassessment.

NNHFPC may revoke the approval for a new food material that fails to meet food safety requirements in the reassessment.

Article 18 A producer of the new food material shall comply with the production requirements as provided in the public notice to guarantee the safety of the new food material.

Article 19 Regarding food that contains new food materials, its label shall comply with laws, regulations, food safety standards, and NHFPC public notice requirements.

Article 20 Practices that violate these rules, and producing or using new food materials that have not passed a safety assessment shall be punished pursuant to relevant provisions in the Food Safety Law.

Article 21 NHFPC will reject acceptance or approval of applications that conceal relevant facts, or contain false material, and issue a warning to the applicant. In addition, the applicant shall not apply for approval of the new food material for one year.

Permission for new food material obtained by inappropriate measures, such as deceit or bribery, shall be revoked by NHFPC.

Article 22 Definition

*De facto* equivalence: if a newly applied for food material is substantially equivalent to other foods or new food material that have already been publicly notified in terms of species, source, biological characteristics, main ingredients, edible parts, dosage level, scope of application and group of people that consume the food, and the processing techniques and quality standards adopted are basically

identical, the new food material is considered equally safe as the traditional food, or the two have substantial equivalence.

Traditionally consumed: refers to a food that has been produced or traded in unified or non-unified package in a province/municipality for over 30 years; in addition, the food is not listed in the Pharmacopoeia of the People's Republic of China.

Article 23 New food materials in these measures do not cover genetically engineered foods, health foods, or new varieties of food additives. Genetically engineered foods, health foods and new varieties of food additives are subject to administration of relevant laws and regulations.

Article 24 These measures will come into force on October 1, 2013. The Administrative Measures on Novel Food promulgated by the former Ministry of Health on December 1, 2007 will be revoked at the same time.

<http://www.moh.gov.cn/fzs/s3576/201307/34de96581cfc4751be3bc83870360472.shtml>

**TRANSLATION END**